MAR 10 2006

K052212

SECTION 4 – 510(k) SUMMARY

[Submitted pursuant to 21 CFR 807.92(a)]

Summary Date: October 17, 2005

1. Submitter Information

Submitter:	Direx Systems Corporation 11 Mercer Road Natick Business Park Natick, MA 01760
Telephone:	(508) 651-0900
Fax:	(508) 651-8125
Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade / Proprietary Name:	*MIGUE*
Classification Name:	Accelerator, Linear, Medical.
Classification Name/ Product code:	90 IYE
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.5050

3. Predicate Devices

3Dscope K041213

ExacTrac X-Ray 6D K040585

4. Device Description

MIGUE is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures. MIGUE uses x-ray registration as the method of locating the position of the patient. It is indicated for all body procedures.

The device consists of three units:

1. *MIGUE Main Unit - incorporates two angularly spaced identical Fluoroscopic Channels, mounted on a rigid ring, for acquisition of X-ray images.*
2. Console Workstation – PC with embedded software, used for control, display and image processing.
3. *Electronics Cabinet.*

Principle of operation:

a) Acquire two images, one from each channel.

b) Each channel displays an acquired image and a marker indicating the IsoCenter projection onto the fluoroscopic screen.

5. Indications for Use

MIGUE is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures. MIGUE uses x-ray registration as the method of locating the position of the patient. It is indicated for all body procedures.

6. Technological Characteristics

The Substantial Equivalence table provides a comparison of *MIGUE's* technological characteristics to those of the predicate devices. The table is located in Section 8 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

Ms. Larisa Gershtein
Quality Assurance Manager
Direx Systems Corp.
437 Turnpike Street
CANTON MA 02021

Re: K052212
Trade/Device Name: MIGUE
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 9, 2006
Received: February 10, 2006

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3 – INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K052212

Device Name: MIGUE

Indications for Use:

MIGUE is intended to aid in patient target to radiation beam set-up for administration of radiation therapy. It is indicated for all body procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052212